DEC 27 2005

ANALOGIC®

510(k) Summary
For
Analogic Corporation

FETALGARD Lite-NIBP

1. Date this Summary was Prepared:

July 12, 2005

2. Submitter's Name and Address:

Submitter's Name:	Analogic Corporation
Address:	8 Centennial Drive
City, State, and Zip:	Peabody, MA 01960
Registration Number:	1219601

3. Contact Person:

Name:	Janet R. Kwiatkowski
Title:	Regulatory Affairs
Telephone:	(978) 326-4186
Facsimile:	(978) 977-6808
E-mail:	Jkwiatkowski@analogic.com

4. Device Name:

Proprietary or Trade Name:	FETALGARD Lite-NIBP
Common Name:	Fetal Monitor
Model Name:	FGL-NIBP
Classification Name:	Perinatal Monitoring System
Classification Panel:	Obstetrical and Gynecological Devices
Product Codes:	HGM, DXN
Code of Federal Regulations:	884.2740, 870.1130

Device Panel	CFR Section	Product Code	Device Class	Description
Obstetrical and Gynecological Devices	870.1025	HGM	II	System, monitoring, perinatal
Cardiovascular Devices	870.1130	DXN	II	System, measurement, blood-pressure, non-invasive

5. Predicate Devices:

The legally marketed devices to which equivalence is being claimed are:

The FETALGARD Lite cleared under Premarket Notification K002503. This predicate device was chosen specifically for the fetal heart rate and uterine pressure indications.

The C3 Patient Monitor cleared under Premarket Notification K030931. The applicable part of this predicate device is the non-invasive blood pressure module and heart rate (derived from NIBP) indications.

6. Description of FETALGARD Lite-NIBP

The FETALGARD Lite-NIBP is a compact, lightweight device for measuring, processing, displaying, and printing information derived from four physiological measurements:

- Fetal Heart Rate. Two types of ultrasound transducers can be used to monitor single or twins fetal heart rate and display real-time on the LCD screen or permanently recorded on the optional printer.
- Uterine Activity. Uterine pressure changes via a tocotonometer are used to monitor uterine contractions. The waveforms are displayed real-time on the LCD screen or permanently recorded on the optional printer.
- Maternal non-invasive blood pressure. Blood pressure is measured non-invasively (NIBP) by the oscillometric method.
- Maternal heart rate. The algorithm used to derive maternal heart rate is identical to the derived heart rate parameter used in the C3 Patient Monitor when the NIBP module is the measurement source.

A printer records fetal heart rate and tocotonometer waveforms, maternal non-invasive blood pressure value, and maternal heart rate value.

The FETALGARD Lite-NIBP is powered by internal sealed lead-acid batteries or from the mains supply via an external battery eliminator. A fully charged battery will power the monitor for two hours minimum.

7. Intended Use:

The FETALGARD Lite-NIBP is a Perinatal Monitoring System for non-invasively measuring and showing graphically abdominal contractions, fetal heart rate, maternal non-invasive blood pressure, and maternal heart rate by means of display on a non-permanent graphical display and optionally on a printer. This data is to aid in assessing the well-being of the fetus and mother during the final trimester of pregnancy (non-stress test). This device is for use only by trained medical personnel located in hospitals, clinics, doctors' offices, and patient's home.

8. Comparison of Technological Characteristics:

The technological characteristics of the FETALGARD Lite-NIBP are the same as the legally marketed predicate devices.

9. Non-clinical Tests to be used in Determination of Substantial Equivalence:

Prior to marketing the FETALGARD Lite-NIBP, verification testing activities will be conducted to establish the compliance, performance, and reliability characteristics of the FETALGARD Lite-NIBP. This is to include the following non-clinical tests:

IEC 60601-1 (including Amendments 1 & 2), Medical Electrical Equipment - General Requirements for Safety

IEC 60601-1-2: 2001 Medical electrical equipment - Electromagnetic compatibility emission limits meet Group 1 Class B

IEC 60601-1-4: Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral standard: Programmable electrical medical systems

IEC 60601-1-8 Part 1-8: General requirements for safety - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical system

IEC 60601-2-30 Medical electrical equipment – Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment

IEC 60601-2-49 Medical electrical equipment – Particular requirements for the safety of multifunction patient monitoring equipment

ANSI/AAMI SP10 Manual, Electronic, or Automated Sphygmomanometers

Mechanical shock and vibration tests will be performed in accordance with IEC 60068 series of standards to ensure the device withstands shocks and vibrations in environment of intended use.

Shipping container transportation tests will be performed in accordance with ISTA; Project 2A to ensure packaging of equipment is not adversely affected during shipping.

Altitude tests will be performed to ensure that operation at higher altitudes does not adversely affect electrical safety or performance.

Tests will be performed to verify enclosure material robustness and resistance to cleaning materials commonly used in hospitals.

10. Conclusions from Non-clinical Testing:

The test schedule of the FETALGARD Lite-NIBP combined with "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers," September 1997, Track 1 tests already performed demonstrate that the performance of the FETALGARD Lite-NIBP patient monitor is substantially equivalent to the FETALGARD Lite and the C3 Patient Monitor predicate devices cited in Section 5 of this summary. The device will present no new concerns regarding safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 7 2005

Ms. Janet R. Kwiatkowski
Regulatory Affairs Specialist
Analogic Corporation
8 Centennial Drive
PEABODY MA 01960

Re: K051903
Trade/Device Name: FETALGARD Lite-NIBP Fetal Monitor
Regulation Number: 21 CFR §884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM
Regulation Number: 21 CFR §870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: II
Product Code: DXN
Dated: November 21, 2005
Received: December 5, 2005

Dear Ms. Kwiatkowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

ANALOGIC®

Device Name: FETALGARD Lite-NIBP

Indications for Use Statement

The FETALGARD Lite-NIBP is a Perinatal Monitoring System for non-invasively measuring and showing graphically abdominal contractions, fetal heart rate, maternal non-invasive blood pressure, and maternal heart rate by means of display on a non-permanent graphical display and optionally on a printer. This data is to aid in assessing the well-being of the fetus and mother during the final trimester of pregnancy (non-stress test). This device is for use only by trained medical personnel located in hospitals, clinics, doctors' offices, and patient's home.

Prescription Use (Per 21 CFR 801 Subpart D)	X	~~AND~~/OR	Over-The-Counter Use (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051903